

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

) THIS DOCUMENT RELATES TO:)
))
SHEILA BROWN, et al.)) CIVIL ACTION NO. 99-20593
v.))
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9003

Bartle, J.

February 25, 2013

Demetrius Reid ("Ms. Reid" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Eugene Reid III, Ms. Reid's spouse, and Danielle Reid and Sydney Reid, Ms. Reid's children, also have each submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In January, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Elliot D. Agin, M.D. Dr. Agin is no stranger to this litigation. According to the Trust, he has attested to at least 215 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated May 11, 1998, Dr. Agin attested in Part II of Ms. Reid's Green Form that she suffered from moderate

3. (...continued)

presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

mitral regurgitation and an abnormal left atrial dimension.⁴

Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$567,341.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, James M. Pagano, M.D., F.A.C.C., stated that claimant had "[m]oderate mitral regurgitation." Dr. Pagano, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA").

See Settlement Agreement § I.22.

In September, 2005, the Trust forwarded the claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala concluded that there was no reasonable medical basis for Dr. Pagano's finding that claimant had moderate mitral regurgitation. In support of this conclusion, Dr. Penkala stated that "[t]he tape was very poor in

4. Dr. Agin also attested that claimant suffered from mild aortic regurgitation. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

quality especially the color Doppler portion. The Nyquist limit was set too low and I really do not know how one could accurately assess the [mitral regurgitation] based [on] the study I reviewed."

Based on Dr. Penkala's finding, the Trust issued a post-audit determination denying Ms. Reid's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted a letter from Robert L. McNamara, M.D., M.H.S., F.A.C.C., in which he stated:

From my best assessment and measurements from this technically limited copy of the echocardiographic study, the mitral regurgitant jet area to left atrial area (RJA/LAA) measures 29% in the four chamber view and 26% in the two-chamber view.... Thus, it is my opinion that it is reasonable to conclude moderate mitral regurgitation

....

The Trust then issued a final post-audit determination, again denying Ms. Reid's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Reid's claim.

show cause why Ms. Reid's claim should be paid. On March 31, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6111 (Mar. 31, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 6, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Reid submits the same letter from Dr. McNamara that she submitted in contest. In response, the Trust argues that Dr. McNamara's letter does not establish a reasonable medical basis for Ms. Reid's claim because Dr. McNamara merely repeats Dr. Agin's representation that the echocardiogram demonstrates moderate mitral regurgitation and that he does not challenge Dr. Penkala's finding that the echocardiogram is compromised by a low Nyquist setting.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and stated that no reasonable echocardiographer could conclude that the study demonstrated moderate mitral regurgitation. Specifically, Dr. Vigilante observed:

All of the usual echocardiographic views were obtained. However, the study was not conducted in a manner consistent with medical standards. There was excessive color gain causing significant color artifact within the myocardial tissue and outside of the heart in the parasternal and apical views. An

inappropriately low Nyquist limit of 49 cm per second was noted at a depth of 20 cm in all parasternal and apical views. There was "stuttering" of cardiac images classic for abnormal persistence. Because of these issues, the color Doppler portion of the echocardiogram study was uninterpretable. Neither mitral regurgitation nor aortic regurgitation could be accurately identified on this study....

.... As stated above, color Doppler was uninterpretable and accurate evaluation of the presence or severity of mitral regurgitation was not possible. Therefore, the RJA could not be determined on this study. In addition, pulse wave and continuous wave Doppler were used to interrogate the mitral valve. Significant mitral regurgitation was not suggested with these modalities.

....

... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the color Doppler recordings on the echocardiogram of May 11, 1998 were uninterpretable with comments as above. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study and that the study was conducted in a manner consistent with medical standards.

After reviewing the entire show cause record, we find claimant's arguments without merit. First, claimant does not adequately refute the findings of the auditing cardiologist and the Technical Advisor. Specifically, the auditing cardiologist, Dr. Penkala, noted that "[t]he Nyquist limit was set too low." In addition, Dr. Vigilante noted that claimant's echocardiogram was not performed in a manner consistent with medical standards because "[t]here was excessive color gain causing significant

color artifact" and there was "[a]n inappropriately low Nyquist limit."⁸ Although Ms. Reid obtained a letter from Dr. McNamara after receiving Dr. Penkala's audit, Dr. McNamara does not refute the finding of an inappropriate Nyquist setting. In fact, Dr. McNamara confirmed that the study was "technically limited." Mere disagreement with the auditing cardiologist or Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

We also disagree with claimant that the opinions of Dr. Agin and Dr. McNamara establish a reasonable medical basis for her claim. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating the echocardiogram setting; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow," and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2650 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Penkala and Dr. Vigilante found that the Nyquist limit used

8. Despite an opportunity to do so, Ms. Reid did not submit a response to the Technical Advisor Report. See Audit Rule 34.

in this study was too low. In addition, Dr. Vigilante determined that excessive color gain caused significant color artifact. Claimant did not adequately refute these findings. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Reid's claim for Matrix Benefits and the related derivative claims submitted by her spouse and children.